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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,066	12/02/2003	Martin Zimmerling	1941/172	2565
2101	7590	02/17/2006	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	
DATE MAILED: 02/17/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

### Office Action Summary

Application No.

10/726,066

Applicant(s)

ZIMMERLING ET AL.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 7,8,18-20,23-25,27,28,31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-17,21,22,26,29,30 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Species III in the reply filed on 12/07/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 7-8, 18-20, 23-25, 27-28 and 31-32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/27/05.

### ***Claim Objections***

Claims 4-5 are objected to because of the following informalities: these claims recite the use of the device but positively claim the human body. The human body cannot be a positively claimed part of the human body. It is suggested that applicant amend the claim language to functional claim the human body, i.e. "for implantation in a subject's ear or skull". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-3,6,9-14,16-17 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Prosl et al (USPN 4,541,429). Prosl discloses an implantable magnetically-actuated valve that includes a fluid chamber (24) having an inlet (14) and outlet (16), and an internal magnet (see figure 4) disposed within the fluid chamber. The internal magnet is moveable such that displacement of the internal magnet restricts the flow of fluid through the fluid chamber. See 4:57-58 and 7:44-46. An external magnet (M) provides the magnetic field that moves the internal magnet. See figure 2. The fluid chamber and the housing (coating) of the magnet are made from titanium. The internal magnet is spherical in width and cylindrical in height. The housing includes anchors (72,76). The magnet includes grooves (66). The device is capable of being used in a subject's ear or skull due to the disclosure of implantation and the overall size of the device.

Claims 1-2,4-5,12,26,29-30 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Marion et al (USPN 4,443,214). Marion discloses an implantable valve for use in the skull with a fluid chamber, a fluid inlet and a fluid outlet. An internal rotating magnet is disposed in the chamber. An external magnet is used to change the position of the internal magnet to allow flow through the chamber. See 3:9,45-46,48,62-64 and 4:52-57. Regarding the use of the device, the device is capable of being used in any environment that requires the controlled transfer of fluid. The device being for implantation is therefore capable of being used in any internal application such as in a cochlear implant in the ear.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prosl. Prosl meets the claim limitations as described above but fails to include silicone.

At the time of the invention, it would have been an obvious design choice to make the magnet housing from silicone. Applicant has not disclosed that silicone versus other biocompatible materials solves a problem, is used for a particular purpose or provides an advantage. Furthermore, one would expect applicant's invention and the prior art to perform the valving function equally well when either made from titanium or silicone since both materials are biocompatible.

Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prosl or Marion in view of Rehder et al (USPubN 2002/0108623). Prosl and Marion each independently meet the claim limitation as described above but both fail to include an external indicator including a compass.

However, Rehder discloses an external indicator for use with an implantable magnetically actuated device.

At the time of the invention, it would have been obvious to incorporate the external indicator of Rehder into both the invention of Prosl and also Marion. The motivation would

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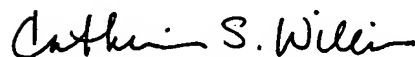
have been in order to locate the device for ease of removal if the device is defective and needs to be replaced. See Summary of Rehder.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams  
February 15, 2006